

REMARKS

The present amendment is responsive to the Notice to Comply issued August 18, 2009. In the Notice to Comply, the examiner required the filing of a CRF and paper copy sequence listing, as well as an amendment specifically directing its entry into the application and a statement that the content of the paper and CRF are the same and include no new matter. The examiner specifically referred to the sequence at page 24, lines 21-22.

Attached hereto is a new sequence listing in the form of a .txt file. It is requested that this new sequence listing be used as both the paper copy and the computer-readable form. Applicants have amended the specification at page 24 to identify the sequences therein as SEQ ID NO:1, and the attached new sequence listing includes this sequence, as supported by the specification as filed. The present amendment further directs entry of the new sequence listing into the application.

The following statement is provided to meet the requirements of 37 C.F.R. §1.821(f) and 1.821(g).

I hereby state, in accordance with 37 C.F.R. §1.821(f), that the .txt file submitted herewith constitutes both the computer readable form as well as the paper copy of the sequence listing, and therefore they are the same.

I hereby also state, in accordance with 37 C.F.R. §1.821(g), that the submission is not believed to include new matter.

Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily

complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

It should be noted that the attached Sequence Listing was run through the USPTO Checker software (Version 4.4.0) (October 25, 2005) and no errors were found.

If the examiner has any questions or comments concerning the sequence listing in the above described application, the examiner is urged to contact the undersigned at the phone number below.

As the present amendment is in full compliance with the requirements of the Notice to Comply of August 18, 2009, entry of this amendment and an indication of full compliance with the sequence disclosure requirements are respectfully urged. Passage of the present application to issue for the reasons set forth in

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Amd. dated September 3, 2009
Reply to Notice to Comply of August 18, 2009

applicant's amendment of June 1, 2009, are hereby earnestly
solicited.

Respectfully submitted,

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